NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

[R08-313]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R3-9-101	Amend
R3-9-106	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 3-526.02

Implementing statutes: A.R.S. § 3-526.02

3. The effective date of the rules:

November 8, 2008

4. A list of all previous notices appearing in the Register addressing the rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 2040, May 23, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 2022, May 23, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Carlos Ramírez, Rules Analyst
Address:	Department of Agriculture 1688 W. Adams St. Phoenix, AZ 85007
Telephone:	(602) 542-0962
Fax:	(602) 542-5420
E-mail:	cramirez@azda.gov

6. An explanation of the rules, including the agency's reasons for initiating the rules:

The Arizona Iceberg Lettuce Research Council, serving in cooperation with the Department of Agriculture, is amending R3-9-101 and R3-9-106 to prescribe requirements for governmental units that wish to apply for Council grants. Governmental units will include any department, commission, council, board, bureau, committee, institution, agency, government corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government. The Department's separate treatment of governmental units when applying for grants is consistent with the differences in how they are treated under Title 41, dealing with grants.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

In fiscal year 2006-2007 the AILRC issued $83,500 in grants. The rulemaking will prescribe guidelines for governmental units to apply for grants, absent the public notification process and the partial distribution requirements. The Council anticipates this will affect applicants for grants by making the process more competitive, but it will also foster further research in advancing the Council's objectives for iceberg lettuce research. It is unlikely the rulemaking will affect public or private employment or the state's general fund. The Council has determined there are no alternative means of achieving the objectives of the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:

The Department erred in its justification in the preceding Notice of Proposed Rulemaking. The Department intended to state that when the AILRC established its grant rules, it prescribed guidelines that applied to all applicants, whether they were persons (as defined by A.R.S. § 41-2701) or governmental units. This made the Council's rules more restrictive than the grant statutes in Title 41, which recognize the difference between persons and governmental units. The rulemaking resolves this restriction by prescribing a grant application process for governmental units while still preserving the openness of the evaluation process by putting consideration of the grant application before the AILRC during an open meeting.

The Department has also made minor revisions to the rule language as suggested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

No comments received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

Not applicable

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

ARTICLE 1. ARIZONA ICEBERG LETTUCE RESEARCH COUNCIL

Section
R3-9-101. Definitions
R3-9-106. Grants

ARTICLE 1. ARIZONA ICEBERG LETTUCE RESEARCH COUNCIL

R3-9-101. Definitions

In addition to the definitions in A.R.S. § 3-526, the following terms apply to this Article:

1. "AILRC" means the Arizona Iceberg Lettuce Research Council.
2. "Authorized signature" means the signature of an individual authorized to receive funds on behalf of the applicant and responsible for the execution of the applicant's project.
3. "Awardee" means a successful applicant to whom the AILRC awards grant funds for research on a specific project.
4. "Department" means the Arizona Department of Agriculture.
5. "Governmental unit" means any department, commission, council, board, bureau, committee, institution, agency, government corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government.

~~5.~~6. "Grant" means an award of financial support to an applicant according to A.R.S. § 3-526.02(B) and (C)(5).

~~6.~~7. "Grant award agreement" means a document that advises an applicant of the amount of money awarded following receipt by the AILRC of the applicant's signed acceptance.

R3-9-106. Grants

A. Grant application process.

1. The AILRC shall award grants according to the competitive grant solicitation requirements of this Article.

2. The AILRC shall post the grant application and manual on the AILRC's web site at least four weeks before the due date of a grant application.
3. The AILRC shall ensure that the grant application manual contains the following items:
   a. Grant topics related to AILRC programs specified by A.R.S. § 3-526.02(B) and (C)(5);
   b. A statement that the information contained in an application is not confidential;
   c. A statement that the AILRC funding source is primarily from per carton assessments on iceberg lettuce grown in Arizona;
   d. An application form including sections about the description of the grant project, scope of work to be performed, an authorized signature line, and a sample budget form;
   e. A statement that the applicant shall not include overhead expenses in the budget for the proposed project;
   f. The criteria that the AILRC shall use to evaluate an application;
   g. The date and time by which the applicant shall submit an application;
   h. The anticipated date of the AILRC award;
   i. A copy of the AILRC grant solicitation rules; and
   j. Any other information necessary for the grant application.
4. The AILRC shall not consider an application received by the AILRC after the due date and time.

B. Criteria. The AILRC shall consider the following when reviewing a grant application and deciding whether to award AILRC funds:
1. The applicant's successful completion of prior research projects,
2. The extent to which the proposed project identifies solutions to current issues facing the iceberg lettuce industry,
3. The extent to which the proposed project addresses future issues facing the iceberg lettuce industry,
4. The extent to which the proposed project addresses the findings of any industry surveys conducted within the previous year,
5. The appropriateness of the budget request in achieving the project objectives,
6. The appropriateness of the proposal time-frame to the stated project objectives, and
7. Relevant experience and qualifications of the applicant.

C. Public participation.
1. The AILRC shall make all applications available for public inspection by the business day following the application due date.
2. Before awarding a grant, the AILRC shall discuss and evaluate grant applications and proposed projects at a meeting conducted under A.R.S. § 38-431 et seq.

D. Evaluation of grant applications.
1. The AILRC may allow applicants to make oral or written presentations at the public meeting if time, applicant availability, and meeting space permit.
2. The AILRC may modify an applicant's proposed project in awarding funding.
3. The AILRC shall notify an applicant in writing of the AILRC's decision to fund, modify, or deny funding for a proposed project within 10 business days of the AILRC decision. The AILRC shall notify applicants by the U.S. Postal Service, commercial delivery, electronic mail, or facsimile.

E. Awards and project monitoring.
1. Before releasing grant funds, the AILRC shall execute a grant award agreement with the awardee. The awardee shall agree to accept the grant's legal requirements and conditions and authorize the AILRC to monitor the progress of the project by signing a grant award agreement.
2. The AILRC shall pay no more than 50% of the grant in the initial payment to the awardee.
3. During the term of the project, the awardee shall inform the AILRC of changes to the awardee's address, telephone number, or other contact information.
4. The AILRC may require an interim written report or oral presentation from the awardee during the pendency of the project.
5. The AILRC shall not award grant funds remaining after the initial payment until the awardee submits to the AILRC:
   a. A final research report, and
   b. An invoice for actual final project expenses not exceeding the remaining portion of the award.
6. The AILRC shall make research findings and reports resulting from any grant awarded by the AILRC available to Arizona iceberg lettuce producers.

F. Repayment. If the awardee does not complete the project as specified in the grant award agreement, the awardee shall return all unexpended grant funds within 30 days after receipt of a written request by the AILRC.

G. Governmental units.
1. The AILRC may request one or more governmental units to submit grant applications as prescribed in subsection (G)(3), without regard to subsections (A), (E)(2), and (E)(5).
2. The AILRC may issue grants to governmental units without regard to subsections (A), (E)(2), and (E)(5).
3. A governmental unit may apply to the AILRC for a grant when there is no pending request for grant applications

under subsection (A) under the following conditions:

a. The application shall include a description of the project, the scope of work to be performed, a budget that does not include overhead expenses, and an authorized signature.

b. The application shall be available for public inspection upon receipt by the AILRC.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE AGRICULTURAL COUNCILS AND COMMISSIONS

[R08-314]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R3-9-201	Amend
R3-9-202	Amend
R3-9-203	Amend
R3-9-204	Amend
R3-9-205	Amend

2. The statutory authority for the rulemaking, including both the authorizing statutes (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 3-584

Implementing statutes: A.R.S. §§ 3-584 and 3-587

3. The effective date of the rules:

November 8, 2008

4. A list of all previous notices appearing in the Register addressing the rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 2040, May 23, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 2025, May 23, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Carlos Ramírez, Rules Analyst

Address: Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

E-mail: cramirez@azda.gov

6. An explanation of the rules, including the agency's reasons for initiating the rules:

The Arizona Grain Research and Promotion Council, serving in cooperation with the Department of Agriculture, is amending its rules to remove the specific grain assessment fee of two cents and replace it with a clause that would allow the Council to set the fee annually within statutory limitations. The objective is to give the Council more flexibility to change the fee in response to grain market fluctuations.

Additionally, the Council is amending R3-9-205 to prescribe requirements for governmental units that wish to apply for Council grants. Governmental units will include any department, commission, council, board, bureau, committee, institution, agency, government corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government. The Council's separate treatment of governmental units when applying for grants is consistent with the differences in how they are treated under Title 41, dealing with grants.

The Council is also amending its rules to make them consistent with grammar and style changes recommended in the Administrative Procedures Act.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying

each study, and any analysis of each study and other supporting material:
Not applicable

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:
Not applicable

9. The summary of the economic, small business, and consumer impact:
In fiscal year 2006-2007 the AGRPC issued $39,328 in grants. The rulemaking will prescribe guidelines for governmental units to apply for grants, absent the public notification process and the partial distribution requirements. The Council anticipates this will affect applicants for grants by making the process more competitive, but it will also foster further research in advancing the Council's objectives for grain research and promotion. It is unlikely the rulemaking will affect public or private employment or the state's general fund. The Council has determined there are no alternative means of achieving the objectives of the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:
The Department erred in its justification in the preceding Notice of Proposed Rulemaking. The Department intended to state that when the AGRPC established its grant rules, it prescribed guidelines that applied to all applicants, whether they were persons (as defined by A.R.S. § 41-2701) or governmental units. This made the Council's rules more restrictive than the grant statutes in Title 41, which recognize the difference between persons and governmental units. The rulemaking resolves this restriction by prescribing a grant application process for governmental units while still preserving the openness of the evaluation process by putting consideration of the grant application before the AGRPC during an open meeting.

The Department has also made minor revisions to the rule language as suggested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency responses to them:
No comments received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
Not applicable

13. Incorporations by reference and their location in the rules:
None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:
Not applicable

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE AGRICULTURAL COUNCILS AND COMMISSIONS

ARTICLE 2. ARIZONA GRAIN RESEARCH AND PROMOTION COUNCIL

Section

ARTICLE 2. ARIZONA GRAIN RESEARCH AND PROMOTION COUNCIL

R3-9-201. Definitions
In addition to the definitions in A.R.S. § 3-581, the following term applies to this Article:
"AGRPC" means the Arizona Grain Research and Promotion Council.

"Department" means the Arizona Department of Agriculture.

R3-9-202. Fees; Grain Assessment and Refund
A. The ~~Arizona Grain Research and Promotion Council~~ AGRPC shall ~~assess a fee of two cents~~ annually prescribe the fee to be assessed per hundredweight of grain sold in Arizona ~~as prescribed~~ within the limitations established under A.R.S. § 3-

587.

B. The person who pays the fee required under subsection (A) shall ensure that:
1. The grain assessment fee is remitted to the ~~Council~~ AGRPC; and
2. The following information is provided to the ~~Council~~ AGRPC on a form obtained from the Department:
   a. First buyer's name, address, and telephone number;
   b. Report date and months covered by the report;
   c. Total amount remitted to the ~~Council~~ AGRPC for the reporting period;
   d. Producer's name, address, and telephone number;
   e. Type of grain and tonnage by grain type; and
   f. First buyer's or designee's signature.

C. Refund.
1. A producer may request a refund as prescribed under A.R.S. § 3-592 and shall provide the following information to the ~~Council~~ AGRPC on a form obtained from the Department:
   a. Producer's name, address, telephone number, and signature;
   b. Name of the first buyer;
   c. Amount of grain sold subject to the refund request; and
   d. First buyer's or designee's notarized signature confirming the purchase, funds withheld, and date remitted to the ~~Council~~ AGRPC.
2. An executive committee member shall authorize a refund as prescribed in A.R.S. § 3-592 if the person requesting the refund complies with the requirements of subsection (B)(1).

R3-9-203. Hearings

A. The ~~Council~~ AGRPC shall use the uniform administrative procedures of A.R.S. Title 41, Chapter 6, Article 10 to govern any hearing before the ~~Council~~ AGRPC required under A.R.S. § 3-591.

B. A party may file a motion for rehearing or review under A.R.S. § 41-1092.09.

C. The ~~Council~~ AGRPC shall grant a rehearing or review of an administrative law decision for any of the following causes materially affecting the moving party's rights:
1. The decision is not justified by the evidence or is contrary to law;
2. There is newly discovered material evidence that could not with reasonable diligence have been discovered and produced at the original proceeding;
3. One or more of the following deprived the party of a fair hearing:
   a. Irregularity or abuse of discretion in the conduct of the proceeding;
   b. Misconduct of the ~~Council~~ AGRPC, the administrative law judge, or the prevailing party; or
   c. Accident or surprise which could not have been prevented by ordinary prudence; or
4. Excessive or insufficient sanction.

D. The ~~Council~~ AGRPC may grant a rehearing or review to any or all of the parties. The rehearing or review may cover all or part of the issues for any of the reasons stated in subsection (C). An order granting a rehearing or review shall particularly state the grounds for granting the rehearing or review, and the rehearing or review shall cover only the grounds stated.

R3-9-204. Records

The Department shall retain the ~~Council's~~ AGRPC's records as prescribed in A.R.S. § 3-586. A record may be reviewed at the Department's main office, Monday through Friday, except an Arizona legal holiday, during the hours of 8:00 a.m. to 5:00 p.m. A copy of a record will be provided according to the provisions of A.R.S. § 39-121 et seq.

R3-9-205. Grants

A. Definitions.

~~1. "AGRPC" means the Arizona Grain Research and Promotion Council.~~

~~2.~~ "Authorized signature" means the signature of an individual authorized to receive funds on behalf of an applicant and responsible for the execution of the applicant's project.

~~3.~~ "Awardee" means an applicant to whom the AGRPC awards grant funds for a proposed project.

"Governmental unit" means any department, commission, council, board, bureau, committee, institution, agency, government corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government.

~~4.~~ "Grant" means an award of financial support to an applicant according to A.R.S. § 3-584(C)(5).

~~5.~~ "Grant award agreement" means a document advising an applicant of the amount of money awarded following receipt by the AGRPC of the applicant's signed acceptance of the award.

B. Grant application process.
1. The AGRPC shall award grants according to the competitive grant solicitation requirements of this Article.
2. The AGRPC shall post the grant application and manual on the AGRPC's web site at least four weeks before the due

date of a grant application.

3. The AGRPC shall ensure that the grant application and manual contain the following items:
   a. Grant topics related to AGRPC projects specified in A.R.S. § 3-584(C)(5);
   b. A statement that the information contained in a grant application is not confidential;
   c. A statement that the AGRPC funding source is primarily from assessments on the seed of barley and wheat of all classes produced in Arizona for use as food, feed, or seed or produced for any industrial or commercial use;
   d. An application form including sections about the description of the grant project, scope of work to be performed, an authorized signature line, and a sample budget form;
   e. A statement that the applicant shall not include overhead expenses in the budget for the proposed project;
   f. The criteria that the AGRPC shall use to evaluate an application;
   g. The date and time by which the applicant shall submit an application;
   h. The anticipated date of the AGRPC award;
   i. A copy of this Section consisting of grant solicitation procedures and requirements; and
   j. Any other information necessary for the grant application.
4. The AGRPC shall not evaluate an application received by the AGRPC after the due date and time.

C. Criteria. The AGRPC shall consider the following when reviewing a grant application and deciding whether to award AGRPC funds:
1. The applicant's successful completion of prior research projects, if applicable;
2. The extent to which the proposed project identifies solutions to current issues facing the grain industry;
3. The extent to which the proposed project addresses future issues facing the grain industry;
4. The extent to which the proposed project addresses the findings of any industry surveys conducted within the previous year;
5. The appropriateness of the budget request in achieving the project objectives;
6. The appropriateness of the proposal time-frame to the stated project objectives; and
7. Relevant experience and qualifications of the applicant.

D. Public participation.
1. The AGRPC shall make all applications available for public inspection by the business day following the application due date.
2. Before awarding a grant, the AGRPC shall discuss, evaluate, and make a decision on grant applications and proposed projects at a meeting conducted under A.R.S. § 38-431 et seq.

E. Evaluation of grant applications.
1. The AGRPC may allow applicants to make oral or written presentations at the public meeting if time, applicant availability, and meeting space permit.
2. The AGRPC may modify an applicant's proposed project in awarding funding.
3. The AGRPC shall notify an applicant in writing of the AGRPC's decision to fund, modify, or deny funding for a proposed project within 10 business days of the AGRPC decision. The AGRPC shall notify applicants by the U.S. Postal Service, commercial delivery, electronic mail, or facsimile.

F. Awards and project monitoring.
1. Before releasing grant funds, the AGRPC shall execute a grant award agreement with the awardee. The awardee shall agree to accept the grant's legal requirements and conditions and authorize the AGRPC to monitor the progress of the project by signing the grant award agreement.
2. The AGRPC shall pay no more than 50% of the grant in the initial payment to the awardee.
3. During the term of the project, the awardee shall inform the AGRPC of changes to the awardee's address, telephone number, or other contact information.
4. The AGRPC may require an interim written report or oral presentation from the awardee during the term of the project.
5. The AGRPC shall not award the grant funds remaining after the initial payment until the awardee submits to the AGRPC:
   a. A final research report, and
   b. An invoice for actual final project expenses not exceeding the remaining portion of the grant funds.
6. The AGRPC shall make research findings and reports resulting from any grant awarded by the AGRPC available to Arizona grain producers.

G. Repayment. If the awardee does not complete the project as specified in the grant award agreement, the awardee shall return all unexpended grant funds within 30 days after receipt of a written request by the AGRPC.

H. Governmental units.
1. The AGRPC may request one or more governmental units to submit grant applications as prescribed in subsection (H)(3), without regard to subsections (B), (F)(2), and (F)(5).
2. The AGRPC may issue grants to governmental units without regard to subsections (B), (F)(2), and (F)(5).
3. A governmental unit may apply to the AGRPC for a grant when there is no pending request for grant applications

under subsection (B) under the following conditions:

a. The application shall include a description of the project, the scope of work to be performed, a budget that does not include overhead expenses, and an authorized signature.

b. The application shall be available for public inspection upon receipt by the AGRPC.

NOTICE OF FINAL RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE AGRICULTURAL COUNCILS AND COMMISSIONS

[R08-311]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R3-9-506 Amend

2. The statutory authority for the rulemaking, including both the authorizing statutes (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 3-468.02

Implementing statutes: A.R.S. § 3-468.02

3. The effective date of the rules:

November 8, 2008

4. A list of all previous notices appearing in the *Register* addressing the rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 2040, May 23, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 2029, May 23, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Carlos Ramírez, Rules Analyst

Address: Department of Agriculture
1688 W. Adams St.
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

E-mail: cramirez@azda.gov

6. An explanation of the rules, including the agency's reasons for initiating the rules:

The Arizona Citrus Research Council, serving in cooperation with the Department of Agriculture, is amending R3-9-506 to prescribe requirements for governmental units that wish to apply for Council grants. Governmental units will include any department, commission, council, board, bureau, committee, institution, agency, government, corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government. The Department's separate treatment of governmental units when applying for grants is consistent with the differences in how they are treated under Title 41, dealing with grants.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

In fiscal year 2006-2007 the ACRC issued $30,000 in grants. The rulemaking will prescribe guidelines for governmental units to apply for grants, absent the public notification process and the partial distribution requirements. The Council anticipates this will affect applicants for grants by making the process more competitive, but it will also foster further research in advancing the Council's objectives for citrus research. It is unlikely the rulemaking will affect

public or private employment or the state's general fund. The Council has determined there are no alternative means of achieving the objectives of the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and the final rules:

The Department erred in its justification in the preceding Notice of Proposed Rulemaking. The Department intended to state that when the ACRC established its grant rules, it prescribed guidelines that applied to all applicants, whether they were persons (as defined by A.R.S. § 41-2701) or governmental units. This made the Council's rules more restrictive than the grant statutes in Title 41, which recognize the difference between persons and governmental units. The rulemaking resolves this restriction by prescribing a grant application process for governmental units while still preserving the openness of the evaluation process by putting consideration of the grant application before the ACRC during an open meeting.

The Department has also made minor revisions to the rule language as suggested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

No comments received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

No

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 9. DEPARTMENT OF AGRICULTURE
AGRICULTURAL COUNCILS AND COMMISSIONS

ARTICLE 5. ARIZONA CITRUS RESEARCH COUNCIL

Section
R3-9-506. Grants

ARTICLE 5. ARIZONA CITRUS RESEARCH COUNCIL

R3-9-506. Grants

A. Definitions.
1. "ACRC" means the Arizona Citrus Research Council.
2. "Authorized signature" means the signature of an individual authorized to receive funds on behalf of the applicant and responsible for the execution of the applicant's project.
3. "Awardee" means a successful applicant to whom the ACRC awards grant funds for research on a specific project.
4. "Governmental unit" means any department, commission, council, board, bureau, committee, institution, agency, government corporation, or other establishment or official of the executive branch or corporation commission of this state, another state, or the federal government.
~~4.~~5. "Grant" means an award of financial support to an applicant according to A.R.S. § 3-468.02(B) and (C)(5).
~~5.~~6. "Grant award agreement" means a document advising the applicant of the amount of money awarded following receipt by the ACRC of the applicant's signed acceptance.

B. Grant application process.
1. The ACRC shall award grants according to the competitive grant solicitation requirements of this Article.
2. The ACRC shall post the grant application and manual on the ACRC's web site at least four weeks before the due date of a grant application.
3. The ACRC shall ensure that the grant application manual contains the following items:
   a. Grant topics related to ACRC programs specified by A.R.S. § 3-468.02(B) and (C)(5);
   b. A statement that the information contained in an application is not confidential;
   c. A statement that the ACRC funding source is primarily from per carton assessments on citrus grown in Arizona;
   d. An application form including sections about the description of the grant project, scope of work to be performed,

an authorized signature line, and a sample budget form;
e. A statement that the applicant shall not include overhead expenses in the budget for the proposed project;
f. The criteria that the ACRC shall use to evaluate an application;
g. The date and time by which the applicant shall submit an application;
h. The anticipated date of the ACRC award;
i. A copy of the ACRC grant solicitation rules; and
j. Any other information necessary for the grant application.

4. The ACRC shall not consider an application received by the ACRC after the due date and time.

C. Criteria. The ACRC shall consider the following when reviewing a grant application and deciding whether to award ACRC funds:
1. The applicant's successful completion of prior research projects,
2. The extent to which the proposed project identifies solutions to current issues facing the citrus industry,
3. The extent to which the proposed project addresses future issues facing the citrus industry,
4. The extent to which the proposed project addresses the findings of any industry surveys conducted within the previous year,
5. The appropriateness of the budget request in achieving the project objectives,
6. The appropriateness of the proposal time-frame to the stated project objectives, and
7. Relevant experience and qualifications of the applicant.

D. Public participation.
1. The ACRC shall make all applications available for public inspection by the business day following the application due date.
2. Before awarding a grant, the ACRC shall discuss and evaluate grant applications and proposed projects at a meeting conducted under A.R.S. § 38-431 et seq.

E. Evaluation of grant applications.
1. The ACRC may allow applicants to make oral or written presentations at the public meeting if time, applicant availability, and meeting space permit.
2. The ACRC may modify an applicant's proposed project in awarding funding.
3. The ACRC shall notify an applicant in writing of the ACRC's decision to fund, modify, or deny funding for a proposed project within 10 business days of the ACRC decision. The ACRC shall notify applicants by the U.S. Postal Service, commercial delivery, electronic mail, or facsimile.

F. Awards and project monitoring.
1. Before releasing grant funds, the ACRC shall execute a grant award agreement with the awardee. The awardee shall agree to accept the grant's legal requirements and conditions and authorize the ACRC to monitor the progress of the project by signing a grant award agreement.
2. The ACRC shall pay no more than 50% of the grant in the initial payment to the awardee.
3. During the term of the project, the awardee shall inform the ACRC of changes to the awardee's address, telephone number, or other contact information.
4. The ACRC may require an interim written report or oral presentation from the awardee during the pendency of the project.
5. The ACRC shall not award the grant funds remaining after the initial payment until the awardee submits to the ACRC:
   a. A final research report, and
   b. An invoice for actual final project expenses not exceeding the remaining portion of the award.
6. The ACRC shall make research findings and reports resulting from any grant awarded by the ACRC available to Arizona citrus producers.

G. Repayment. If the awardee does not complete the project as specified in the grant award agreement, the awardee shall return all unexpended grant funds within 30 days after receipt of written request by the ACRC.

H. Governmental units.
1. The ACRC may request one or more governmental units to submit grant applications as prescribed in subsection (H)(3), without regard to subsections (B), (F)(2), and (F)(5).
2. The ACRC may issue grants to governmental units without regard to subsections (B), (F)(2), and (F)(5).
3. A governmental unit may apply to the ACRC for a grant when there is no pending request for grant applications under subsection (B) under the following conditions:
   a. The application shall include a description of the project, the scope of work to be performed, a budget that does not include overhead expenses, and an authorized signature.
   b. The application shall be available for public inspection upon receipt by the ACRC.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 20. BOARD OF DISPENSING OPTICIANS

[R08-310]

PREAMBLE

1. Sections Affected | **Rulemaking Action**

R4-20-110	Amend
R4-20-118	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1673

Implementing statutes: A.R.S. §§ 32-1671, 32-1673, 32-1684.01, 32-1685, 32-1686, 32-1691, 32-1691.01, 32-1693, 32-1694, 32-1695, 32-1696, 32-1697, 32-1698, 32-1699

3. The effective date of the rule:

November 8, 2008

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 13 A.A.R. 4219, November 30, 2007

Notice of Proposed Rulemaking: 14 A.A.R. 450, February 15, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Lori D. Scott, Executive Director
Address:	1400 W. Washington St., Rm 230 Phoenix, AZ 85007
Telephone:	(602) 542-3095
Fax:	(602) 542-3093
E-mail:	director@asbdo.state.az.us

6. An explanation of the rule, including the agency's reasons for initiating the rulemaking:

The rule provides detailed licensing and regulatory information and procedural instructions. The Board is amending R4-20-110 for clarification on licensing of an optical establishment. R4-20-118 is amended to require opticians to maintain a copy of the customer's prescription and a record of optical devices dispensed. This will better ensure that the optical devices dispensed actually match the prescription. This rule will also clarify acts or omissions that constitute unprofessional conduct.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

The proposed amendments do not diminish a previous grant of authority of a political subdivision of this state.

9. A summary of the economic, small business, and consumer impact:

This rulemaking will impact licensed opticians and establishments by clarifying qualifications already set forth in statute for establishment licensing and ensuring they will maintain a copy of the customer's prescription for three years. As the majority of locations already keep a copy of the prescription this will be a minimal impact. The costs to the Board are moderate for promulgation of the rules. The Board's administrative and staff costs to implement the rules are minimal. The Secretary of State's cost for publishing the rules is minimal. The cost for review of the rules by the Governor's Regulatory Review Council is minimal. The cost of licensed opticians and establishments to review new rules is minimal.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:

None

11. A summary of comments made regarding the rule and the agency response to them:

Written comments have been received on behalf of the Arizona Optometric Association. Comments indicated that the Association does not agree that optometrists who own dispensing practices should obtain an Establishment license issued by the Dispensing Opticians Board. The comment asserts that licensed optometrists acting within the scope of their practice, which includes dispensing prescription eyewear, are not subject to regulation by the Dispensing Opticians Board.

The agency's response is that the Board is not trying to regulate optometrists, ophthalmologists, or their staff, as they are clearly exempted in A.R.S. § 32-1691, but to require the company, corporation, partnership, firm, association or society who owns the optical establishment to be licensed by the Board as required by A.R.S. § 32-1684.01 The Board has always maintained that a sole proprietor optometrist or ophthalmologist who owns an optical establishment would not be required to obtain an establishment license. The Board does want to clarify that anyone who is part of, or forms, any corporation, company, partnership, firm, association or society that intends to operate an optical establishment is required to obtain an optical establishment license because these are separate legal entities.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Any material incorporated by reference and its location in the rule:

None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

No

15. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 20. BOARD OF DISPENSING OPTICIANS

ARTICLE 1. GENERAL

Section
R4-20-110. Application for an Optical Establishment License; Qualifications
R4-20-118. Unprofessional Conduct

ARTICLE 1. GENERAL

R4-20-110. Application for an Optical Establishment License; Qualifications

A. Any person, corporation, company, partnership, firm, association or society operating an optical establishment, except those exempt under A.R.S. § 32-1691, shall obtain an optical establishment license.

B. An applicant for an optical establishment license shall submit an application packet to the Board that contains:

1. An application form provided by the Board, signed and dated by the applicant, and notarized that contains:
   a. The applicant's name, establishment name, establishment address, and telephone number. An application form shall be signed by the following:
      i. If a sole proprietorship, the individual owning the optical establishment;
      ii. If a corporation, each individual owning 20% or more of the voting stock in the corporation;
      iii. If a partnership, the managing partner and a general partner;
      iv. If a limited liability company, the designated manager, or if no manager is designated, any two members of the limited liability company;
   b. The hours the establishment will be open to the public for business;
   c. If applicable, the name, business address, and telephone number of each licensed optical establishment currently being operated by the applicant in Arizona;
   d. If a corporation, the name of the statutory agent, the corporation's officers, and the state of incorporation; and
   e. The name, business address, telephone number, and license number of each licensed dispensing optician who is scheduled to work at the establishment on a full-time basis, consisting of 32 hours or more per week;
2. If a corporation, the articles of incorporation; and
3. The fee required in R4-20-112.

C. To be licensed, an optical establishment shall employ at least one dispensing optician licensed by the Board, for at least 32 hours or more per week.

R4-20-118. Unprofessional Conduct

In addition to actions specified in A.R.S. § 32-1696, unprofessional conduct in the practice of optical dispensing includes the

following:

1. Substandard care as specified in R4-20-119;
2. Failing to maintain a copy of the customer's prescription and ~~or~~ failing to prepare and maintain a record of optical devices dispensed for at least three years. The record of optical devices dispensed shall include the brand, style, and size of the frame, if any, and the style, material, and all other information necessary to accurately reproduce each lens. The ~~records~~ record shall be separate from optometrists' or physicians' records;
3. Failing or refusing to make a copy of a prescription or record described in subsection (2) promptly available to the customer~~,~~ who is the subject of the prescription or record, the customer's designated representative, the customer's prescribing practitioner, or the Board or its investigator, when requested. Notwithstanding this provision, a dispensing optician need not make the record of contact lenses dispensed on a trial basis available to the customer; ~~and~~
4. Failing or refusing to take corrective action or investigate a customer complaint concerning the manufacture or fit of eyeglasses, contact lenses, or other optical devices dispensed at the establishment by which the dispensing optician is employed if there is a substantial basis for the complaint;
5. Failure of any person, corporation, company, partnership, firm, association or society to maintain an active optical establishment license as required by R4-20-110; and
6. Failure to comply with a Board order.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-301]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-301	Amend
R4-23-601	Amend
R4-23-613	Amend
R4-23-1003	Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. §§ 32-1904(B)(3) and (7), 32-1984(F), and 36-2523

3. The effective date of the rules:

November 8, 2008

4. A list of all previous notices appearing in the *Register* addressing the proposed rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 535, February 22, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 1482, May 2, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
1700 W. Washington St., Suite 250
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: dwright@azpharmacy.gov

6. An explanation of the rules, including the agency's reasons for initiating the rules:

A.R.S. § 32-1984 specifies that distributors and purchasers (including pharmacies) of prescription-only drugs must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs for at least three years. R4-23-601 (General Provisions), R4-23-613 (Procedure for Discontinuing a Pharmacy), and R4-23-1003 (Records and Order Forms) allow the above-mentioned records to be

kept for only two years. To be consistent with the statute, the Board is amending R4-23-601, R4-23-613, and R4-23-1003 to replace the two-year record retention requirement with a three-year record retention requirement.

The Board determined that with the present National Association of Boards of Pharmacy (NABP) licensure process, it is not necessary to have an intern provide a recent photograph with their application for licensure. The photograph requirement, specified in R4-23-301(H)(2)(e), will be deleted by this rulemaking. The Board also determined that it is too burdensome to have foreign graduate applicants provide the original Foreign Pharmacy Graduate Examination Committee (FPGEC) certification document required in R4-23-301(H)(2)(f). There have been instances where the original document was lost in the mail before arriving at the Board office. R4-23-301(H)(2)(f), which becomes subsection (e) after deleting the photograph requirement, is amended by deleting the words "an original" and inserting the words "a notarized copy of the applicant's." The use of a notarized copy of the FPGEC certification document will provide the necessary proof that the applicant took and passed the required Foreign Pharmacy Graduate Examination without taking the chance of losing an original document in the mail. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that amending these rules will benefit the public and the pharmacy community by clearly establishing practice standards for pharmacy interns, and pharmacies. These rules will also benefit the public and the pharmacy community by clearly establishing uniform recordkeeping standards for the receipt, disposal, and inventory of drugs and controlled substances in Arizona.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rules.

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The amended rules will impact the Board, pharmacists, interns, and pharmacies. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The amended rules will have minimal economic impact on pharmacists and pharmacies. The rules are necessary to make the rules consistent with statute, specifically A.R.S. § 32-1984. The amendments to R4-23-601, R4-23-613, and R4-23-1003 will bring those rules back to the three-year record retention requirement that was in place until July 12, 2006. The three-year record retention is required by statute and will result in a minimal increase in recordkeeping costs for pharmacies. The amended rules will provide a minimal cost savings for intern applicants by removing the cost of a photograph. The cost of a notarized copy of a Foreign Pharmacy Graduate Examination certification document is minimal compared to the cost of replacing an original document lost in the mail. The amended rules have no economic impact on the public.

The amended rules will benefit the public and the pharmacy community by clearly establishing practice standards for pharmacy interns and pharmacies. These rules will also benefit the public and the pharmacy community by clearly establishing uniform recordkeeping standards for the receipt, disposal, and inventory of drugs and controlled substances in Arizona.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

A public hearing was held June 9, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Any material incorporated by reference and its location in the rules:

None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-301. Intern Licensure

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-601. General Provisions
R4-23-613. Procedure for Discontinuing a Pharmacy

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

Section
R4-23-1003. Records and Order Forms

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

A. No change
B. No change
1. No change
2. No change
3. No change
4. No change

C. No change
D. No change
1. No change
2. No change
3. No change

E. No change
F. No change
1. No change
2. No change

G. No change
H. Intern application. An applicant for licensure as a pharmacy intern or graduate intern shall:
1. No change
2. File an application on a form furnished by the Board, that includes:
   a. No change
   b. No change
   c. No change
   d. No change
   ~~e. A recent photograph of the applicant that is no larger than 2 1/2" x 3" with the applicant's signature on the front;~~
   ~~f.~~e. If the applicant graduated from an unapproved college or school of pharmacy, ~~an original~~ a notarized copy of the applicant's Foreign Pharmacy Graduate Examination Committee (FPGEC) certification document;
   ~~g.~~f. No change
   ~~h.~~g. No change

I. No change
J. No change
K. No change
1. No change
2. No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

A. No change
1. No change

2. No change

B. No change

C. No change

D. Record of receipt and disposal of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

1. Every person manufacturing a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, including repackaging or relabeling, shall prepare and retain for not less than ~~two~~ three years the manufacturing, repackaging, or relabeling date for each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.
2. Every person receiving, selling, delivering, or disposing of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall record and retain for not less than ~~two~~ three years the following information:
   a. No change
   b. No change
   c. No change
   d. No change
3. No change
4. No change

E. No change

R4-23-613. Procedure for Discontinuing a Pharmacy

A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 14 days before discontinuing operation of the pharmacy. The notice shall contain the following information:

1. No change
2. No change
3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical will be kept and the person responsible for the records. These records shall be kept for a minimum of ~~two~~ three years from the date the pharmacy is discontinued;
4. No change
5. No change

B. No change

C. No change

D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:

1. No change
2. No change
3. All controlled substances are transferred as follows:
   a. No change
   b. No change
   c. Keep the original of the inventory with the discontinued pharmacy's records of narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical purchase and disbursement for a minimum of ~~two~~ three years from the date the pharmacy is discontinued;
   d. No change
   e. No change

E. No change

F. During the ~~two-year~~ three-year record retention period specified in subsection (A)(3), the person described in subsection (A)(3) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.

G. No change

ARTICLE 10. UNIFORM CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1003. Records and Order Forms

A. Records.

1. If the pharmacist-in-charge of a pharmacy is replaced by another pharmacist-in-charge, the new pharmacist-in-charge shall complete an inventory of all controlled substances in the pharmacy within 10 days of assuming the responsibility. This inventory and any other required controlled substance inventory shall:
   a. Include an exact count of all Schedule II controlled substances;
   b. Include an exact count of all Schedule III through Schedule V controlled substances or an estimated count if the

stock container contains fewer than 1001 units;
c. Indicate the date the inventory is taken and whether the inventory is taken before opening of business or after close of business for the pharmacy;
d. Be signed by:
i. The pharmacist-in-charge; or
ii. For other required inventories, the pharmacist who does the inventory;
e. Be kept separately from all other records; and
f. Be available in the pharmacy for inspection by the Board or its designee for not less than ~~two~~ three years.
2. A loss of a controlled substance shall be reported:
a. Within 10 days of discovery;
b. On a DEA form 106;
c. By the pharmacist-in-charge of a pharmacy or a manufacturer;
d. By the permittee or ~~manager~~ designated representative of a full-service wholesaler; and
e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.
3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain for not less than ~~two~~ three years the manufacturing, repackaging, or relabeling date for each controlled substance.
4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than ~~two~~ three years the following information:
a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
d. The date of each transaction.
5. A full-service drug wholesale permittee or the designated representative shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or designated representative shall conduct this inventory:
a. On May 1 of each year or as directed by the Board; and
b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a designated representative.
6. A drug manufacturer permittee or the pharmacist-in-charge shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or pharmacist-in-charge shall conduct this inventory:
a. On May 1 of each year or as directed by the Board; and
b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a pharmacist-in-charge.

B. Order form. For purposes of A.R.S. § 36-2524, "Order Form" means DEA Form 222c.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-303]

PREAMBLE

1. Sections Affected **Rulemaking Action**
R4-23-411 Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. §§ 32-1901(1), (23), and (69)

3. The effective date of the rule:

November 8, 2008

4. A list of all previous notices appearing in the *Register* addressing the proposed rule:

Notice of Rulemaking Docket Opening: 13 A.A.R. 4543, December 21, 2007

Notice of Proposed Rulemaking: 14 A.A.R. 746, March 7, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. An explanation of the rule, including the agency's reasons for initiating the rule:

During the November 15, 2007 Board meeting, the Board determined that several changes to R4-23-411 (Pharmacist-administered Immunizations) should be made as requested by the Arizona Pharmacy Alliance and interested pharmacists. The changes include the following: replacing the words "hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster" with the word "adult" throughout the rule, adding the words "of vaccines in the Center's for Disease Control (CDC) recommended adult immunization schedule and vaccines recommended in the CDC's Health Information for International Travel" after the word "immunizations" in the second sentence of R4-23-411(A), and inserting the word "adult" after the words "pharmacist-administered" wherever found in the rule. The changes will allow certified immunization pharmacists to administer FDA-approved adult vaccines to an adult with a valid prescription order and increase the availability and reduce the cost of necessary adult vaccines for Arizona citizens. The rule includes format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of this rule will benefit the public health and safety by clearly establishing standards for pharmacist-administered adult immunizations.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The amended rule will impact the Board, pharmacists, pharmacies, and the public. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rule will have minimal economic impact on pharmacists and pharmacies. The rulemaking will increase the number of vaccines that a pharmacist certified to give immunizations may administer to adult patients. This increases the number of patients a pharmacist may serve and increases the public's access to needed vaccines. Being able to administer a larger number of vaccines provides pharmacists or pharmacies with opportunity for increased income. The number of vaccines that can be administered by a pharmacist will increase from six to 16. The Board estimates that the increase in the number of vaccines available for administration by pharmacists will provide a potential increased income from immunizations for pharmacies of from 20 to 50 percent.

The amended rule will have moderate to substantial economic impact on the public. The public will benefit from increased access to immunization services from pharmacists, including many more vaccines previously not provided by pharmacists. The Board estimates that the public could save from 40 to 60 percent by using a pharmacy for vaccinations instead of a scheduled doctor's office visit.

The Board believes that approval of this rule will benefit the public health and safety by clearly establishing standards for pharmacist-administered adult immunizations.

10. A description of the changes between the proposed rule, including supplemental notices, and final rule (if applicable):

There are no substantial changes in the final rule from the proposed rule. At the request of G.R.R.C. staff, the Board incorporated by reference the Center for Disease Control's Recommended Adult Immunization Schedule, published October 1, 2008 and the CDC Health Information for International Travel 2008, published May 15, 2007. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rule and the agency response to them:

A public hearing was held April 7, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Any material incorporated by reference and its location in the rule:

The Center for Disease Control's Recommended Adult Immunization Schedule, published October 1, 2008, and no future amendments or editions, located at R4-23-411(A).

CDC Health Information for International Travel 2008, published May 15, 2007, and no future amendments or editions, located at R4-23-411(A).

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

No

15. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-411. Pharmacist-administered Adult Immunizations

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered Adult Immunizations

A. Authority to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult. As used in this Section, "adult" means an eligible patient 18 years of age or older. If a pharmacist meets the qualifications and standards specified by this Section and the Board certifies the pharmacist, the pharmacist may, upon receipt of a valid prescription order, administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster immunizations~~ vaccines listed in the Center for Disease Control's (CDC) Recommended Adult Immunization Schedule, published October 1, 2008, and no future amendments or editions, which is incorporated by reference, vaccines recommended in the CDC Health Information for International Travel 2008, published May 15, 2007, and no future amendments or editions, which is incorporated by reference, and, in an emergency, epinephrine and diphenhydramine to an eligible adult patient ~~18 years of age and older upon receipt of a valid prescription order~~. The documents incorporated by reference are on file with the Board and available from the CDC at http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm and http://wwwn.cdc.gov/travel/contentYellowBook.aspx. The Board shall certify a pharmacist who meets the qualifications established in subsection (B). A pharmacist who has authority to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult shall not delegate the authority to any other pharmacist or employee.

B. Qualifications for authorization to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult. After receipt of a completed application form, the Board shall issue a certificate authorizing the administration of ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult to a pharmacist who meets the following qualifications:

1. Has a current, unrestricted license to practice pharmacy in this state;
2. Successfully completes a training program specified in subsection (C); and
3. Has a current certificate in basic cardiopulmonary resuscitation.

C. Pharmacist-administered adult immunizations training program requirements. A training program for pharmacists to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, including administering epi-

nephrine and diphenhydramine to counteract the adverse effects of an immunization given based on a patient-specific prescription order received before administering the immunization;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (D).

D. Recordkeeping and reporting requirements.
1. In addition to filing the prescription order as required in A.R.S. § 32-1964, a pharmacist granted authorization under this Section to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult shall provide to the pharmacy ~~and the pharmacist-in-charge shall maintain in the pharmacy for a minimum of seven years~~ the following documentation regarding each immunization administered:
   a. The name, address, and date of birth of the patient;
   b. The date of administration and site of injection;
   c. The name, dose, manufacturer's lot number, and expiration date of the vaccine ~~or, in an emergency~~, epinephrine, or diphenhydramine;
   d. The name and address of the patient's primary health care provider, as identified by the patient;
   e. The name and address of the prescribing medical practitioner, if different from the patient's primary health care provider;
   f. The name of the pharmacist administering the immunization;
   g. A record of the pharmacist's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
   h. The date that the written report specified in subsection (D)(2) was sent to the patient's primary health care provider;
   i. Consultation or other professional information provided to the patient by the pharmacist; and
   j. The name of the vaccine information sheet provided to the patient.
2. The pharmacist shall provide a written report to the patient's primary health care provider containing the documentation required in subsection (D)(1) within 14 days of the immunization. The pharmacy shall make the required records specified in subsection (D)(1) available in the pharmacy for inspection by the Board or its designee.
3. A pharmacy's pharmacist-in-charge shall maintain the records required in subsection (D)(1) in the pharmacy for a minimum of seven years from the immunization's administration date.

E. Confidentiality of records. A pharmacist, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.

F. Renewal of a certificate for pharmacist-administered adult immunizations. A certificate authorizing a pharmacist to administer ~~hepatitis, influenza, meningococcal, pneumococcal, smallpox, and tetanus booster~~ immunizations and, in an emergency, epinephrine and diphenhydramine to an adult shall be renewed biennially by submitting a renewal request within the 30 days before the certificate's expiration date. ~~Any~~ A pharmacist desiring to renew the certificate shall provide to the Board proof of the following:
1. Current certification in basic cardiopulmonary resuscitation, and
2. Completion of a minimum of two contact hours (0.2 CEU) of continuing education related to immunizations. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-300]

PREAMBLE

1. Sections Affected — **Rulemaking Action**
R4-23-615 — Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule is implementing (specific):

Authorizing statutes: A.R.S. § 32-1904(A)(1)

Implementing statutes: A.R.S. § 32-1904(B)(3)

3. The effective date of the rule:

November 8, 2008

4. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 14 A.A.R. 718, February 29, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 1489, May 2, 2008

5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 250 Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. An explanation of the rule, including the agency's reasons for initiating the rule:

R4-23-615 (Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form) in subsection (B) prohibits a pharmacy permittee or pharmacist-in-charge from allowing any drug previously counted by a mechanical storage and counting device that has not left the pharmacy from being returned to the drug's original cell, cassette, or stock bottle. The Board is aware that there are pharmacies who through technology, such as bar coding, can ensure that a drug previously counted by a mechanical storage and counting device that has not left the pharmacy is safe to return to the drug's cell or cassette. In such pharmacies, the label that is affixed to the drug container now can include the drug's manufacturer, name, strength, and lot number. The pharmacy's system can then scan the container label and the cell or cassette label and correctly match the drug with the cell or cassette, thus allowing the drug to be returned to the proper cell or cassette. The amended rule adds an exception to R4-23-615(B) to allow a previously counted drug that has not left the pharmacy to be returned to its cell or cassette if the Board or its designee approves the drug return method. The amended rule adds a new subsection (G) to R4-23-615 specifying the requirements for Board approval of a drug return method. The rule includes format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that amending this rule will benefit the public health and safety by establishing clear standards for the use of mechanical storage and counting devices, including the safe return of previously counted drug that has not left the pharmacy to the correct drug's cell or cassette within a mechanical storage and counting device.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rules.

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

The rule has little economic impact except the cost to the Board for the usual rulemaking-related costs, which are minimal. The Board will have to approve the return method used by a pharmacy, which includes the cost of a Board Compliance Officer's inspection of the drug return method, which is minimal. The rule does not require a pharmacy to return a drug to a cell or cassette, but a pharmacy that chooses to return a drug to its cell or cassette must use an approved method. The Board estimates the rule will have minimal if any economic impact on pharmacies. A pharmacy might save some staff time by not manually counting drugs previously counted by a device. The Board cannot quantify the time savings that might occur. The rule does not impose any costs on small business or consumers.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, and understandable. The rule benefits the public health and safety by establishing clear standards for the use of mechanical storage and counting devices, including the safe return of previously counted drug that has not left the pharmacy to the correct drug's cell or cassette within a mechanical storage and counting device.

10. A description of the changes between the proposed rule, including supplemental notices, and final rule (if applicable):

There are no substantial changes in the final rules from the proposed rules. During its March 20, 2008 board meeting, the Board approved deleting the word "original" from R4-23-615(B) and (G) in the proposed rule. Before publishing the Notice of Proposed Rulemaking, the Board staff made the requested change to R4-23-615(B), but inadvertently failed to make the change to R4-23-615(G). To correct the error, the final rule is changed by deleting the word "original" from R4-23-615(G) reflecting the Board's intent to remove that word from the final rule. A copy of the Board

meeting minutes from March 20, 2008 is attached for reference. This is not a substantial change. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rule and the agency response to them:

A public hearing was held June 9, 2008. Janet Elliott representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Elliott provided written comment from The Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Any material incorporated by reference and its location in the rule:

None

14. Were the rules previously made as emergency rules and if so, whether the text was changed between the making as an emergency and the making of the final rules:

No

15. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-615. Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-615. Mechanical Storage and Counting Device for a Drug in Solid, Oral Dosage Form

A. No change
1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
3. No change

B. A pharmacy permittee or pharmacist-in-charge shall ensure that any drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy is not returned to the drug's ~~original~~ cell, cassette, or stock bottle, unless the drug return method is approved by the Board or its designee as specified in subsection (G). This subsection does not prevent a pharmacy permittee or pharmacist-in-charge from using a manual or mechanical counting device to count and dispense a previously counted drug that has not left the pharmacy if the previously counted drug is dispensed before its beyond-use-date.

C. No change
1. No change
2. No change
3. No change

D. No change

E. No change
1. No change
2. No change
3. No change
4. No change
5. No change

F. No change

G. Returning a drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy to the drug's cell or cassette.

1. Before returning a drug previously counted by a mechanical storage and counting device that has not left the pharmacy to the drug's cell or cassette, a pharmacy permittee or pharmacist-in-charge shall:
   a. Apply for approval from the Board or its designee for the drug return method to be used in returning the drug;
   b. Develop a drug return method that uses technology, such as bar coding, to prevent drug return errors;
   c. Provide documentation depicting the drug return method;
   d. Demonstrate the drug return method for a Board Compliance Officer; and
   e. Receive approval from the Board or its designee for the drug return method to be used in returning the drug.
2. Before approving a request to waive the drug return prohibition in subsection (B), the Board or its designee shall:
   a. Receive a request in writing from the pharmacy permittee or pharmacist-in-charge;
   b. Review the documentation of the drug return method; and
   c. Receive a satisfactory inspection report from a Board Compliance Officer that the drug return method uses technology to prevent drug return errors.